LETTER FROM THE EDITOR

Just as this issue was being prepared for publication, the US Food and Drug Administration approved a new drug, linaclotide (Linzess, Ironwood Pharmaceuticals/Forest Pharmaceuticals), for the treatment of chronic constipation and irritable bowel syndrome with constipation (IBS-C). Given the limited number of therapies available for these conditions, the approval of this new drug could represent a significant advance in the treatment of these prevalent and difficult-to-treat conditions.

As discussed by Brian E. Lacy and coauthors in the review on page 653 of this month's issue, both chronic constipation and IBS-C affect a significant number of patients—up to 15% of the US population for chronic constipation—and treatment options for these conditions remain limited. While dietary modification and over-the-counter therapies are effective for some patients, other patients require prescription therapy. Prior to the approval of linaclotide, lubiprostone (Amitiza, Sucampo) was the only prescription medication available for the treatment of chronic constipation and IBS-C.

Given that linaclotide just gained approval on August 30th, few clinicians have personal experience with this drug to date, but the published safety and efficacy data appear promising. In a phase III study of linaclotide that was recently published online ahead of print in the *American Journal of Gastroenterology*, 804 patients were evaluated over a 26-week period, and treatment with linaclotide was found to yield significant improvements in abdominal pain, rate of complete spontaneous bowel movements (CSBMs), and other endpoints. Using a composite endpoint that defined responders as those patients who met predefined criteria for improvements in both abdominal pain and CSBM rate, the study found that 34% of patients in the linaclotide treatment group were responders, compared to only 14% of patients in the control group.

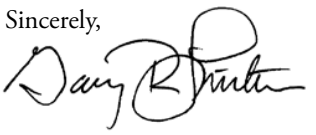
While these data are encouraging, clinicians should keep several points in mind when considering linaclotide as a possible treatment for patients with chronic constipation or IBS-C. First, several side effects have been reported with this drug; diarrhea is the most common adverse event, but patients have also reported abdominal pain, flatulence, headache, viral gastroenteritis, abdominal distention, upper respiratory tract infection, and sinusitis. In addition, linaclotide is only approved for use in adults; it is specifically contraindicated in pediatric patients up to the age of 6 years, and the product label states that use of linaclotide should be avoided in pediatric patients aged 6–17 years.

Despite these limitations, the approval of this new drug represents a significant advance in the treatment of constipation. By giving clinicians another medical option for the treatment of constipation, linaclotide will hopefully allow more patients to be successfully treated, thus dramatically improving their quality of life.

In addition to the timely review of linaclotide by Lacy and colleagues, this month's issue of *Gastroenterology & Hepatology* also includes a review of various noninvasive tests that can aid in the diagnosis of nonalcoholic steatohepatitis and liver fibrosis in patients with nonalcoholic fatty liver disease. This month's columns address how to implement protease inhibitor–based therapy for hepatitis C virus infection; how to manage eosinophilic esophagitis from childhood to adulthood; the diagnosis and treatment of inflammatory bowel disease in older patients; the importance of nutritional assessment in patients with chronic liver disease; and the use of endoscopic ultrasound for management of severe, refractory gastrointestinal bleeding. This month's cases include a patient with metastatic amelanotic melanoma of the jejunum who was diagnosed on capsule endoscopy and a patient with idiopathic myointimal hyperplasia of mesenteric veins that presented as refractory pancolitis.

Finally, I welcome everyone who will be attending this year's American College of Gastroenterology meeting to visit the exhibit hall and stop by our booth (#413). I look forward to seeing many of you in Las Vegas!

Sincerely,



Gary R. Lichtenstein, MD, AGAF, FACP, FACG